EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Sterility Check of Pre-Sterilized and Autoclaved Laboratory Supplies

SOP Number: QC-12-02

Date Revised: 09-19-02

Prepared By: _____ Date: ___/___/___

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Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____

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1.0 SCOPE AND APPLICATION:

1.1 This protocol describes the methods used to determine the sterility of pre-sterilized laboratory supplies and autoclaved glassware. This is a standard quality control practice.

2.0 DEFINITIONS:

2.1 FTM = Fluid thioglycollate medium, typically tubes contain 10 mL of FTM unless stated otherwise.

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES:

5.1 All pre-sterilized laboratory supplies will be inspected upon receipt for damage or torn packaging. Cracked petri-dishes or pipettes may puncture packaging and allow contaminating organisms to enter. Undetected damage to products may interfere with the interpretations of test data by compromising the sterility of the items used in testing.

5.2 Following prolonged storage, autoclaved glassware can become contaminated with aerial microorganisms and compromise the sterility of the glass container. Thus, storage only up to 3 months will be allowed.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable about sterile culture practices and procedures. Documentation of training and familiarity with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

10.1 Autoclaved Glassware: An active inventory for autoclaved glassware is established each month (1st week). Glassware will be labeled with month and year on each item. Glassware that is over 3 months old will be removed and resterilized. If the stored glassware has compromised seals, it will be removed and resterilized.

10.2 Pre-sterilized Supplies:

10.2.1 One (1%) percent of each lot of all pre-sterilized supplies (i.e., 1 mL, 2 mL, 5 mL, 10mL and 25 mL pipettes, plastic petri dishes, membrane filters, plastics loops, dacron swabs, sterile surgical gloves) must be checked for sterility.

10.2.2 Fluid thioglycollate is the culture medium used for sterility testing of pre-sterilized supplies. Duplicate tubes are prepared per item assayed; one tube is incubated at 37±1°C, the other is incubated at 55±1°C, for 5 to 7 days.

10.2.3 Pipettes with volumes of 1 mL, 2 mL, 5 mL and 10 mL are tested by drawing up the respective amount of medium from a 10 mL FTM tube and redispensing the volume back into the original tube. Then dispense half of the total volume into duplicate tubes of FTM.

10.2.4 Large pipettes with volumes of 20 mL and 25 mL are tested by drawing up approximately 10 mL of FTM into the pipette and rotating it to wet the whole inside area, taking care not to wet the cotton plug. Redispense the volume back into the original tube. Dispense half of the total volume into duplicate tubes of FTM.

10.2.5 Petri dishes are tested by adding 10 mL of FTM into each petri dish and swirling across the entire surface. Dispense half of the total volume into duplicate tubes of FTM.

10.2.6 Membrane filters, dacron swabs and plastic loops are cultured by aseptically transferring the entire item or tip of the item to an FTM tube. The tips of swabs and loops are removed using flame sterilized scissors.

10.2.7 Sterile surgical gloves are cultured by aseptically (using flame sterilized scissors) cutting the end of the fingertips of a set of gloves and placing them into a flask with 50-100 mL FTM. The flask is swirled. Then aseptically transfer half of the FTM into duplicate sets of flasks each containing 25-50 mL FTM. Incubate one flask at 37±1°C and the other one at 55±1°C.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Data will be recorded promptly, legibly, and in indelible ink on the appropriate form. Completed forms are archived in notebooks kept in locked file cabinets in the file room D217. Only authorized personnel have access to the locked files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 The OPP Microbiology Laboratory conforms to 40CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated into each SOP.

13.2 Supplies must be inspected for damage upon receipt and findings must be documented.

13.3 Supplies will be used in the order received and tested.

13.4 Culture media utilized in this test procedure will be subjected to standard sterility and viability checks.

13.5 For quality control purposes, the required information is documented on the appropriate forms (see 16.1 and 16.2).

13.6 Autoclaved glassware will be stored on the shelf for a maximum of 3 months. After 3 months, the glassware must be re-autoclaved.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any pre-sterilized laboratory supply which fails the sterility test will be labeled as contaminated, the entire lot identified and returned to the manufacturer, and a new lot requested for replacement.

14.2 Any autoclaved glassware that is over 3 months old will be resterilized before use.

15.0 REFERENCES: None

16.0 FORMS AND DATA SHEETS:

16.1 Autoclaved Glassware Inventory Form

16.2 Sterility Check of Pre-Sterilized Laboratory Supplies

Autoclaved Glassware Inventory Form

OPP Microbiology Laboratory

Yearly Inventory Record for 2002		
Month/Date	Initials	Comments
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		

Sterility Check of Pre-Sterilized Laboratory Supplies

OPP Microbiology Laboratory

Supply Name	Control Number	Lot/Quantity	Date/Initials	No. Tested	37°C ±1°C	55°C ±1°C	Date/Initials	